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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,895

11/04/2005

Jeffrey Yeung

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2268

23429

7590

01/21/2011

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EXAMINER

EISENBERG, REBECCA E

ART UNIT

PAPER NUMBER

3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,895	<b>Applicant(s)</b> YEUNG ET AL.	
	<b>Examiner</b> REBECCA E. EISENBERG	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/18/2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 and 75-98 is/are pending in the application.
- 4a) Of the above claim(s) 75-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/04/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-55, drawn to a device.

Group II, claim(s) 75-98, drawn to a conduit.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Ouchi discloses a device for deployment of a conduit including: a sheath 3; a conduit fitting partially within the sheath; a needle received in the conduit; and an actuator to deploy the conduit (Figs. 12, 39, 41, 45 and 73, col. 17, lines 25-67 and col. 18), Which does not require the use of a sheath. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it requires a conduit that is sized and configured to fit at least partially within a sheath. The subcombination has separate utility such as a catheter.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

The inventions have acquired a separate status in the art in view of their different classifications.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

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shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Carol Titus on January 7, 2010 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 75-98 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19, 20, 53, 54 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "pore size" is not given adequate structural recitation to support this term, it is unclear whether the conduit is made of a porous material, has openings, or pores. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-3, 5, 8, 15-16, 24-33, 37-40, 45, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,964,740 to Ouchi (Ouchi).

Ouchi discloses a device for deployment of a conduit including: a sheath 3; a conduit fitting partially within the sheath; a needle received in the conduit; and an actuator to deploy the conduit (Figs. 12, 39, 41, 45 and 73, col. 17, lines 25-67 and col. 18).

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Regarding claims 32 and 33, Ouchi discloses an embodiment in which a second elastic needle is provided along with a first elastic needle (Figs. 72-73, col. 25, lines 54- 67 and col. 26, lines 1-59). It is noted that Ouchi meets the limitation "the second elastic needle located at least partially around the first elastic needle" in that the first elastic needle is near the second elastic needle.

10. Claims 1, 3, 5, 8, 14-17, 24-31, 35-40, 45, 51 are rejected under 35

U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,595,958 to Mickley (Mickley).

Mickley discloses a device for deployment of a conduit including: a sheath 106 having a sharp tip; a needle 136 located partially within the sheath and having a beveled tip; a conduit 126 partially around the needle; and a plunger or actuator to deploy the conduit (Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

Regarding claims 8 and 14-17, Mickley discloses that conduit 126 can be made of any of various metallic and non-metallic biocompatible materials, including non-biodegradable materials such as polypropylene or polyurethane or biodegradable materials such as polycaprolactone.

11. Claims 1, 3-4, 8, 14-17, 24-31, 35-40, 45 and 50 are rejected under 35

U.S.C. 102(e) as being anticipated by Mickley.

Using an alternate interpretation of Mickley, Mickley discloses a device for deployment of a conduit including: a sheath 106 having a sharp tip; a needle 126 located partially within the sheath and having a beveled tip; a conduit 136 received within the needle; and a plunger or actuator to deploy the conduit (Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

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Regarding claims 8 and 14-17, Mickley discloses that conduit 126 can be made of any of various metallic and non-metallic biocompatible materials, including non-biodegradable materials such as polypropylene or polyurethane or biodegradable materials such as polycaprolactone.

12. Claims 24-30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,190,353 to Makower et al. (Makower).

Makower teaches a conduit deployment device including: a sheath 192 with a side opening 198; a needle 102; and a conduit 194 (Fig. 6e and col. 32, lines 4-36).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 6-7, 18, 23, 41-44 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Mickley in view of U.S. Patent No. 5,041,100 to Rowland et al. (Rowland).

Mickley discloses all elements of the claimed invention except for a coating on the sheath and/or the conduit and/or the needle.

Rowland teaches coating medical instruments to reduce friction. Rowland also teaches including therapeutic agents such as inhibitors of cell or tissue growth in the coating (col. 1, lines 28-68 and col. 2).



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Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating on the sheath of the Mickley device, as taught by Rowland et al., to reduce friction and/or inhibit tissue growth.

15. Claims 9, 13, 46, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mickley.

Mickley discloses all elements of the claimed invention except for conduit 126 being made of a multi-filament biocompatible material. It is noted that Mickley discloses reinforcing the sheath with a braided wire.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed conduit 126 of a braided wire, since it was well known in the art to reinforce a tubular member with braided wire.

Mickley discloses all elements of the claimed invention except for conduit 126 being made of a multi-filament biocompatible material and having an a monofilament portion. It is noted that Mickley discloses reinforcing the sheath with a braided wire.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed conduit 126 of a braided wire, since it was well known in the art to reinforce a tubular member with braided wire during deployment and to have a mono filament portion for insertion into the patient in order to minimize the damage done to the surrounding tissues.

16. Claims 6-7, 18, 23, 41-44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mickley in view of Rowland.

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Using the alternate interpretation of Mickley as seen above, Mickley discloses all elements of the claimed invention except for a coating on the sheath and/or the conduit and/or the needle.

Rowland teaches coating medical instruments to reduce friction. Rowland also teaches including therapeutic agents such as inhibitors of cell or tissue growth in the coating (col. 1, lines 28-68 and col. 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating on the sheath of the Mickley device, as taught by Rowland et al., to reduce friction and/or inhibit tissue growth.

17. Claims 19-20, 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mickley in view of U.S. Patent No. 6,623,474 to Ponzi.

Using the alternate interpretation above of Mickley, Mickley discloses all elements of the claimed invention except for openings or pores in conduit 136.

Ponzi teaches providing openings in a needle or conduit to permit fluid flow out the side of the needle as well as out the distal end (col. 6, lines 49-61).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided openings, as taught by Ponzi, in the Mickley conduit 136, to permit fluid flow out of the side of the conduit as well as the distal end for enhanced dispersion.

Regarding the size of the openings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided openings in the range of 200 microns to 10 nanometers, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

18. Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower in view of Rowland.

Makower disclose all elements of the claimed invention except for a coating on the sheath and/or the conduit and/or the needle.

Rowland teaches coating medical instruments to reduce friction. Rowland also teaches including therapeutic agents such as inhibitors of cell or tissue growth in the coating (col. 1, lines 28-68 and col. 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating on the sheath of the Makower device, as taught by Rowland et al., to reduce friction and/or inhibit tissue growth.

19. Claims 6-7, 23, 41-44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi in view of Rowland.

Ouchi discloses all elements of the claimed invention except for a coating on the sheath and/or the conduit and/or the needle.

Rowland teaches coating medical instruments to reduce friction. Rowland also teaches including therapeutic agents such as inhibitors of cell or tissue growth in the coating (col. 1, lines 28-68 and col. 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating on the sheath of the Ouchi device, as taught by Rowland et al., to reduce friction and/or inhibit tissue growth.

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20. Claims 10-12, 21, 47-48, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi in view of U.S. Patent No. 5,800,484 to Gough et al. (Gough). Ouchi teaches the claim limitations of claim 1, but fails to teach a conduit as a sponge formed of biocompatible material.

Gough teaches a conduit as a sponge formed of biocompatible material (Col. 6 ln. 26-42).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have the sponge of Gough with the device of Ouchi in order to allow the conduits to be moldable and formable to irregular structures and surfaces.

Ouchi teaches the claim limitations of claim 1, but fails to teach a conduit with multiple protrusions extending therefrom.

Gough teaches a conduit with multiple protrusions (see fig. 1, col. 3 ln. 39-50, col. 4 ln. 46-54).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a conduit with multiple protrusions in order to treat multiple areas simultaneously.

Ouchi in view of Gough teach the claim limitations of claim 10, where Gough teaches the protrusions in the form of flanges (see fig. 1).

Ouchi teaches the claim limitations of claim 1, but fails to explicitly teach a tube located around a central portion of the conduit.

Gough teaches a tube located around a central portion of the conduit (Col. 6 ln. 26-41).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to have a tube around a central portion of the conduit in order to reinforce the structure and to provide stability to the conduit.

Ouchi teaches the claim limitations of claim 24, but fails to teach a conduit as a sponge formed of biocompatible material.

Gough teaches a conduit as a sponge formed of biocompatible material (Col. 6 ln. 26-42).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have the sponge of Gough with the device of Ouchi in order to allow the conduits to be moldable and formable to irregular structures and surfaces.

Ouchi teaches the claim limitations of claim 24, but fails to teach a conduit with multiple protrusions extending therefrom.

Gough teaches a conduit with multiple protrusions (see fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a conduit with multiple protrusions in order to treat multiple areas simultaneously.

Ouchi teaches the claim limitations of claim 24, but fails to explicitly teach a tube located around a central portion of the conduit.

Gough teaches a tube located around a central portion of the conduit (Col. 6 ln. 26-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a tube around a central portion of the conduit in order to reinforce the structure and to provide stability to the conduit.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA E. EISENBERG whose telephone number is (571)270-5879. The examiner can normally be reached on Monday - Friday 9:30 AM - 7:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NICHOLAS LUCCHESI can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REBECCA E. EISENBERG/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

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